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Re: Case No.: 1:08-cv-030096; *U. S. ex rel. Hanks v. US Oncology Specialty, LLP, et al.*

Dear Judge Johnson:

Relator Don Hanks submits this letter brief pursuant to the Court's Order in re Motion Hearing entered October 8, 2014.

1. Affirmative Defense – Claims that Kickbacks Fall Within a "Safe Harbor."

Defendants seek dismissal of the Complaint on the grounds that their conduct falls within a "safe harbor" exception to the Anti-Kickback Statute, 42 U.S.C. § 1320a–7b(b). Whether the rebates or other kickbacks a Defendant received from Amgen, Inc. ("Amgen") were reportable or fit within a safe harbor, however, raises a question that cannot be decided on a motion to dismiss. *See* Relator's Memorandum in Opposition to Defendants' Motions to Dismiss ("Mem.") (Dkt. 150) at 8; *U.S. ex rel. Bartlett v. Ashcroft*, CIV.A. 3:04-57, 2014 WL 4179862 *17 (W.D.Pa. Aug. 21, 2014) (safe harbor claim is an affirmative defense). Further, to receive protection under a safe harbor, "a business arrangement must fit squarely within [it]; substantial compliance is not enough . . . ." *Bartlett, supra* (quoting *U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F.Supp.2d 39, 47 (D.Mass.2011).

Discount arrangements, such as the one here, in which federal healthcare programs get less than their proportional share of cost-savings on items or services payable by the programs are deemed "seriously abusive." They result in overcharges to the programs and are not protected by either the statutory exception or the regulatory safe harbor for some types of discounts. *See* 64 Fed. Reg. 63526 (Nov. 19, 1999). The Anti-Kickback Statute prohibits *any payment or other remuneration* by a drug company to a physician as an inducement to the physician to write prescriptions for the company's drugs. 42 U.S.C. § 1320a–7b(b). Under the statute, it is illegal to "knowingly and willfully make [ ] or cause [ ] to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program . . . ." 42 U.S.C. § 1320a–7a(1). Under the statute, it is illegal to "knowingly and willfully . . . receive [ ] any remuneration (including

any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--in return for purchasing . . . any good . . . or item for which payment may be made in whole or in part under a Federal health care program," 42 U.S.C. § 1320a–7b(b)(2). *See Kester v. Novartis Pharm. Corp.*, 88 Fed. R. Serv.3d 1261, at *19 "The [statute] defines 'remuneration' as including 'transfers of items or services for free or for other than fair market value.'" *U.S. ex rel. Fair Lab. Practices Assocs. v. Quest Diagnostics Inc.*, No. 05 Civ. 5393(RPP), 2011 WL 1330542, at *2 (S.D.N.Y. Apr.5, 2011), *aff'd sub nom., United States v. Quest Diagnostics Inc.*, 734 F.3d 154 (2d Cir.2013) (quoting 42 U.S.C. § 1320a–7a(i)(6)). *Cf. Bartlett, supra* (citing cases); *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir.1989) (cited in *U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 47 (D.Mass.2011)); Complaint, ¶ 135. The Defendants nevertheless claim that they were not required to disclose the discounts, rebates and free goods they *earned* and were paid by Amgen simply for buying the "Covered Drugs" (*see* Complaint, ¶ 5), which allowed them, because of the fraud scheme, to be "over-reimbursed" by Government Healthcare Programs for *more than* their cost of these drugs.

Defendants rely upon a safe harbor provision requiring the discount meet one of two specific criteria: that it "be made at the time of the sale of the good or service" or that "the terms of the rebate . . . be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service . . . ." 42 C.F.R. § 1001.952(h)(iii). There are three reasons why Defendants' discount arrangement with Amgen did not qualify for the safe harbor: (1) the discounts were not made at the time of sale; (2) the terms of the discounts were not "fixed" because (a) if the Defendant made additional purchases during a calendar quarter it could receive a greater discount and (b) not all the purchase incentives, such as "overfill," were identified; and (3) the individual supply contracts did not disclose that the discounts and rebates were made to induce purchases of the Covered Drugs. Mem. at 7-8.

The safe harbor provision defines "discount" as a "reduction in the amount a buyer . . . is charged for an item or service based on an arms-length transaction." 42 C.F.R. § 1001.952(h)(5); *see U.S. ex rel. Banigan v. Organon USA Inc.*, 883 F.Supp.2d 277, 296 (D.Mass.2012). The term "discount" does not include "other remuneration, in cash or in kind, not explicitly described in paragraph (h)(5) of this section." 42 C.F.R. § 1001.952(h)(5)(vii). Nor does it embrace collateral kickbacks or reductions in price which are not passed on to the Government Healthcare Program that pays for the good or service. 42 C.F.R. § 1001.952(h)(5)(i)-(iii); *cf. U.S. ex rel. Lisitza v. Johnson & Johnson*, 765 F.Supp.2d 112, 125 (D.Mass.2011) (rejecting defendant's invocation of safe harbor provisions because "[w]hile the raw amounts of the rebates may have been disclosed, the terms and conditions of their payment were not"). Although the Defendants contend, for the first time in a Reply Brief, that the Department of Health and Human Services, Office of the Inspector General, in 2013, issued an opinion letter approving a discount program they contend is factually similar to that alleged here (*see* Reply of Northwest Georgia Oncology Centers at 7, n.4 (Dkt. 151)), that letter, by regulation, has "no application to any individual or entity that does not join in the request for the opinion." 42 C.F.R. § 1008.53; *U.S. ex rel. McDonough v. Symphony Diagnostic Servs., Inc.*, 2:08-CV-00114, 2014 WL 3906461 (S.D. Ohio Aug. 12, 2014). Further, such opinion letters are not entitled to any judicial deference. *Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000).

2. First-to-File Rule – Dismissal Under Fed. R. Civ. Proc. 12(b)(1).

At oral argument, United States Oncology Specialty, LP argued that it should dismissed from this lawsuit based upon the claims made in the *Piacentile* case in which United States Oncology Network was named as a defendant. Yet, United States Oncology Specialty fails to cite to a single Second Circuit case that supports the proposition that the first-to-file bar applies to a related corporate entity that was not previously named in any *qui tam* lawsuit. That is because there is no such case, and nowhere in the *Piacentile* case was United States Oncology Specialty, LP named as a defendant. It is puzzling that United States Oncology Speciality, LP seeks to argue that the naming of a different corporate entity in a different *qui tam* case should be considered as though it, not the other entity, was alleged to have filed false claims. There is no legal support for its position on this issue in this circuit.

Defendant United States Oncology Specialty, LP also specifically conceded during oral argument for the *Piacentile* case that the *Piacentile* complaint does not include the use of overfill (¶¶ 185-192). *Piacentile* also does not include off-invoice discounts (Compl., ¶¶ 181-184), price protection (¶¶ 193-194), free goods (¶¶ 195-196), and other improper incentives (¶¶ 205, 207-210)—many of Relator Hanks' allegations against it. Thus, clearly as to these issues, Hanks' claims cannot be barred under the "first-to-file" rule since the *Piacentile* complaint contains no mention of these allegations at all.

3. Rule 9(b) –Failure to Allege Fraud with Sufficient Particularity.

Defendants seek dismissal of the Complaint on the grounds that it does not allege fraud with sufficient particularity. In fact, it does. *See, e.g.*, Complaint ¶ 77 (describing Amgen's strategy to drive sales by using off-invoice discounts and back-end rebates, noting how, because of Amgen's failure to include these price reductions in its pricing disclosures, the defendant oncology practices stood to gain through the over-reimbursement of charges by Government Healthcare Programs); ¶ 78 (describing rebate structure); ¶ 81 (describing segmentation of buyers into classes based on potential to increase purchases); ¶ 89 (describing details of manner in which target volumes to qualify for rebates were set); ¶ 90 (noting that contractual terms changed from contract to contract); ¶¶ 99-101 (identifying percentage of total sales of Covered Drugs paid for by Government Healthcare Programs). Moreover, the false claims are clearly identified. Relator alleges that *all* the claims filed by the defendants during the Covered Period (Complaint, ¶ 2) for which they sought "reimbursement" from Government Healthcare Programs for the Covered Drugs were false (*id*., ¶ 104). Thus, there can be no question that "defendants can reasonably 'identify particular false claims for payment that were submitted to the government.'" *See U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 11 CIV. 8196 CM, 2014 WL 4401275 (SDNY Sept. 4, 2014) (McMahon, J.) (quoting *U.S. ex rel. Karvelas v. Melrose–Wakefield Hospital*, 360 F.3d 220, 232 (1st Cir. 2004)).

> Courts in this Circuit have repeatedly held that "[i]n cases where the alleged fraudulent scheme is extensive and involves 'numerous transactions that occurred over a long period of time, . . . it [is] impractical to require the plaintiff to plead the specifics with respect to each and every instance of fraudulent conduct [to

> comply with Rule 9(b)].' Pleading the specifics of thousands of claims would be 'cumbersome, unwieldy, and would accomplish no purpose.'" *[U.S. ex rel.] Kester [v. Novartis Pharma. Corp.]*, 88 Fed. R. Serv.3d 1261, at *15 (quoting *In re Cardiac Devices*, 221 F.R.D. [318] at 333, 338 [D.Conn.2004]); *see [U.S. ex rel.] Mooney [v. Americare, Inc.]*, 2013 WL 1346022, at *3 [(EDNY)] ("Courts in this Circuit have . . . relaxed the pleading requirement 'in cases involving complex fraudulent schemes or those occurring over a lengthy period of time . . . .'" (quoting *U.S. ex rel. Tiesinga v. Dianon Sys., Inc.*, 231 F.R.D. 122, 123 (D.Conn.2005)).

U.S. ex rel. Bilotta v. Novartis Pharm. Corp., 2014 WL 4922291 (SDNY Sept. 30, 2014). *See also Simington v. Lease Finance Group, LLC*, 2012 WL 651130 at *10-11 (SDNY) (holding that "'[t]he very nature of the scheme, as alleged, [gave] rise to the reasonable inference' that all defendants . . . 'were involved in the fraud,'" and declining to dismiss under Rule 9(b) because facts were "peculiarly" within defendants' knowledge).

4. Claimed Public Disclosures Do Not Qualify as "Public Disclosures" Under the False Claims Act.

In order to avoid "parasitic" lawsuits, the False Claims Act bars those lawsuits where the essential allegations in the complaint were all publicly disclosed. Such is not the case here.

Counsel's argument as to public disclosure misstates the standard in the Second Circuit as to what is required in order to qualify as a public disclosure. At oral argument, Defendants stated that "the *Kirk* court said in the Second Circuit, we follow the on-the-trail standard." (RT, 16:13-14). That is flatly not true. In *U.S. ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94 (2d Cir.2010), the Court cited to *Kirk* in reviewing the position taken by the United States as *amicus curiae*. *Id*. at 210. The *Kirk* court cites to the "on-the-trail" language in *U.S. ex rel. Springfield Terminal Ry. v. Quinn*, 14 F.3d 645 (D.C.Cir.1994), but it does so in support of the broader position that "our interpretation of §3730(e)(4)(A) accords with that urged by the government as amicus curiae" that "citizen relators will be able to bring suit in those instances in which the government itself is not pursuing, or considering the pursuit of, an investigation." *Id*. at 210. In other words, *Kirk* entirely supports Relator's position. In this case, the United States has declined intervention and, thus, Relator Hanks should be able to "bring [his] own resources to bear where the government [i]s not in a position to act. This division of labor will maximize efficient enforcement of the FCA in the manner envisioned by the authors of the 1986 amendments." *Id*. at 211.

The recent case of *U.S. ex rel. Kester v. Novartis Pharms. Corp.*, *supra*, sharply undercuts Defendants' position. In *Kester*, the court concluded there was no public disclosure where not a single Defendant was named. In other words, these public statements cannot be "public disclosures" because none involve the material elements of the fraud as to the specific defendants at issue. *Id*. at *54 ("These publications did not name any specific pharmacies or drug companies involved in such partnerships or contracts.") In *Kester* where there was no mention of the specific pharmacies or drug companies, there were no

public disclosures that applied and Kester's claims against were allowed to proceed in their entirety. This court should apply the same common-sense logic evident in *Kester*: Where there are only general, vague public reports that do not name a single actual Defendant, these reports cannot be considered public disclosures as to the specific Defendants named in the *qui tam*.

In *Kester*, where a single defendant, Caremark, was named in public disclosures, the court limited the relator's claims as to that defendant, stating that the relator could pursue his claims *after* the effective date of the amendments to the public disclosure bar – March 23, 2010. *Id*. at *45. This Court could, therefore, find that there had been a public disclosure under the old statutory language, but then limit any application until the new amendments became effective in 2010, although we submit that even under the prior provision, there has been no public disclosure. Defendants' arguments are wholly insufficient as to the public disclosure bar modifications instituted at that time as all of Defendants' moving papers *ignore* this 2010 standard entirely. This Court could then preserve these post-2010 claims.

Finally, Relator qualifies as an "original source." Defendants argued that Relator has to be an original source of the public disclosures in this Circuit. (RT 20:18-23). That requirement, however, was squarely rejected by the Supreme Court. *See* U.S. v. Huron Consulting Group, Inc., 843 F. Supp. 2d 464, 471 (S.D.N.Y.2012) ("In Rockwell, however, the Supreme Court directly rejected Long Island Lighting's reading of the text of the public disclosure bar.")

5. Leave to Amend Should be Allowed.

To the extent that this Court is inclined to rule there has been a failure to allege fraud with sufficient particularity, leave to amend should be granted. The Hanks Declaration filed concurrently with Relator's Opposition shows that the Relator is capable of pleading the fraud with greater particularity as to each of the Defendants and should be afforded the opportunity to do so. In Relator's declaration, he identifies the specific kickbacks received by each Defendant Oncology Practice from Amgen over the course of a period of several years. *See* Hanks Decl., Exs. A, B, and C.

6. Conclusion.

Defendants throw a hodge-podge of every conceivable argument against Relator's Complaint in a feverish attempt to have it dismissed before a single deposition has been taken. Each of these arguments is unavailing. Relator requests that this Court deny each of these motions and allow this case to proceed to discovery forthwith. Only after evidence has been taken can the merits of the parties' claims and defenses be properly assessed.

Sincerely,

/ s /

Hays Gorey, Jr.